PATENT COOPERATION TREA

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
BSCI02100WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2007/060581	16/01/2007	01/02/2006
Applicant		
BOSTON SCIENTIFIC SCIMED, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [X] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title**,
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,
   [ ] the text is approved as submitted by the applicant
   [X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,
   a. the figure of the **drawings** to be published with the abstract is Figure No. 2a
      [X] as suggested by the applicant
      [ ] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

Form PCT/ISA/210 (first sheet) (April 2005)

JRW
ENTERED Comment Abstract
DUE: _____

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A medical device includes a carrier and an agent. The agent is formulated to control inflammation of biological tissue, such as heart tissue, and is releasably coupled to the carrier. The carrier (130) is configured to be disposed in operative proximity to the biological tissue to be treated by the agent (120). In one embodiment, the carrier is configured to release the agent or otherwise deliver the agent to the biological tissue, thus controlling inflammation of the tissue. Also, a method to improve healing of biological tissue includes placing a medical device proximate to the heart of a patient, where the medical device has a carrier and an agent configured to control inflammation, the agent is releasably coupled to the carrier. In one embodiment, the method includes causing the agent to be released from the carrier.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/060581

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/67991 A (YANG JUN [US]) 20 September 2001 (2001-09-20) page 4, line 4 - page 10, line 6	1-3, 15-22
X	EP 1 518 517 A (SUN BIOMEDICAL LTD [BM]) 30 March 2005 (2005-03-30) the whole document	1-3, 15-22
X	EP 1 600 125 A (BARD INC C R [US]) 30 November 2005 (2005-11-30) claims; figures	1-3, 15-22
X	WO 99/40874 A (STEINKE THOMAS A [US]) 19 August 1999 (1999-08-19) abstract	1-3, 15-22
X	EP 1 600 122 A (MEDTRONIC VASCULAR INC [US]) 30 November 2005 (2005-11-30) claims; figures	1-3, 15-22

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the International filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 March 2007	16/08/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	SERRA I VERDAGUER, J

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/060581

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple Inventions In this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the Invention first mentioned in the claims; it is covered by claims Nos.:

see additional sheet(s)

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1, 2, 3, 15-20, 21, 22

A stent comprising a drug

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2. claims: 1, 4-6, 21, 23

A patch comprising a drug

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3. claims: 1, 7, 8, 21, 24

A microsphere comprising a drug

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4. claims: 1, 9, 10, 21, 25

A solidifying spray solution comprising a drug

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5. claims: 1, 11, 21, 26

An injectable gel comprising a drug

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6. claims: 1, 12, 13, 21, 27

An injectable paste comprising a drug

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7. claims: 1, 14, 21, 28

An implantable plug comprising a drug

INTERNATIONAL SEARCH REPORT

rmation on patent family members

International application No
PCT/US2007/060581

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0167991 A	20-09-2001	AU 4356701 A	24-09-2001
		US 6379382 B1	30-04-2002
		US 2002062147 A1	23-05-2002
EP 1518517 A	30-03-2005	NONE	
EP 1600125 A	30-11-2005	DE 69926644 D1	15-09-2005
		DE 69926644 T2	18-05-2006
		EP 1117351 A2	25-07-2001
		ES 2247826 T3	01-03-2006
		JP 2003526392 T	09-09-2003
		WO 0018331 A2	06-04-2000
WO 9940874 A	19-08-1999	AT 314023 T	15-01-2006
		AU 754566 B2	21-11-2002
		AU 2239499 A	30-08-1999
		CA 2322050 A1	19-08-1999
		CN 1292668 A	25-04-2001
		DE 69929175 T2	22-06-2006
		EP 1056414 A1	06-12-2000
		JP 3749437 B2	01-03-2006
		JP 2002502665 T	29-01-2002
		RU 2217098 C2	27-11-2003
		US 6033436 A	07-03-2000
		US 6224626 B1	01-05-2001
EP 1600122 A	30-11-2005	NONE	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/060581	16.01.2007	01.02.2006

International Patent Classification (IPC) or both national classification and IPC
INV. A61F2/06

Applicant
BOSTON SCIENTIFIC SCIMED, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	see form PCT/ISA/210	SERRA I VERDAGUER, J Telephone No. +49 89 2399-8198

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1, 2, 3, 15-20, 21, 22

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1, 2, 3, 15-20, 21, 22
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1, 2, 3, 15-20, 21, 22
Industrial applicability (IA)	Yes:	Claims	1, 2, 3, 15-20, 21, 22
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item IV

Lack of unity of invention

This Authority considers that there are 7 inventions covered by the claims indicated as follows:

I: Claims 1, 2, 3, 15-20, 21, 22 directed to a stent comprising a drug
II: Claims 1, 4-6, 21, 23 directed to a patch comprising a drug
II: Claims 1, 7, 8, 21, 24 directed to a microsphere comprising a drug
IV: Claims 1, 9, 10, 21, 25 directed to a solidifying spray solution comprising a drug
V: Claims 1, 11, 21, 26 directed to an injectable gel comprising a drug
VI: Claims 1, 12, 13, 21, 27 directed to an injectable paste comprising a drug
VII: Claims 1, 14, 21, 28 directed to an implantable plug comprising a drug

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The technical features of the independent claims 1 and 21 are a carrier and an agent formulated to control inflammation provided on the carrier. Claims 1 and 21 are not novel since the features therein disclosed are already known from the prior art (e.g. WO-A-01/67991). Moreover, the concept of providing a drug on a carrier to control inflammation in order to improve the healing process is also already known from the prior art (e.g. WO-A-01/67991). Therefore, lack of unity a posteriori arises since the above groups of claims are neither linked by novel and inventive features nor by a common inventive concept. In conclusion, the groups of claims define 7 different inventions.

The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:
   D1: WO 01/67991 A (YANG JUN [US]) 20 September 2001 (2001-09-20)
   D2: EP-A-1 518 517 (SUN BIOMEDICAL LTD [BM]) 30 March 2005 (2005-03-30)
   D3: EP-A-1 600 125 (BARD INC C R [US]) 30 November 2005 (2005-11-30)

D4: WO 99/40874 A (STEINKE THOMAS A [US]) 19 August 1999 (1999-08-19)
D5: EP-A-1 600 122 (MEDTRONIC VASCULAR INC [US]) 30 November 2005 (2005-11-30)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D1 discloses (claims 1 and 15): a medical device (100), comprising an agent (104, 106) formulated to control inflammation of heart tissue to prevent the deterioration of myocardial scaffold after a myocardial infarct; and a carrier (102) to which the agent is releasably coupled, the carrier being configured to be disposed in operative proximity to the heart tissue to be treated by the agent.

3. The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 21, which therefore is also considered not new.

4. Dependent claims 2, 3, 15-20 and 22 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty or inventive step, see documents D1 to D5 and the corresponding passages cited in the search report.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT). If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003